DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
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Denver, Colorado 80225-0087
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September 30, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kevin D. Ostler
President
Lasermed, Inc.
8050 South 1300 West
Salt Lake City, Utah 84123

Ref. #: DEN-02-18

Dear Mr. Ostler:

On July 31-August 1, 2002, Investigator Nicholas R. Nance of our office conducted an inspection of Lasermed, Inc., Salt Lake City, UT. Our investigator determined that your firm manufactures various products, including dental-composite curing lasers. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

1. Failure of management to establish a quality policy, quality plan or quality system procedures as required by 21 CFR 820.20.

2. Failure to establish procedures for quality audits and conduct such audits as required by 21 CFR 820.22.

3. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met as required by 21 CFR 820.30.

4. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications as required by 21 CFR 820.70.

5. Failure to establish and maintain procedures to control product that does not conform to specified requirements as required by 21 CFR 820.90.

6. Failure to establish and maintain procedures for implementing corrective and preventative action as required by 21 CFR 820.100.

7. Failure to maintain device master records that include device specifications, production process specifications and quality assurance procedures as required by 21 CFR 820.181.

8. Failure to maintain device history records that demonstrate the device is manufactured in accordance with the device master record as required by 21 CFR 820.184.

9. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints as required by 21 CFR 820.198.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the Federal regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations are corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in FDA initiating regulatory action without further informal notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed

Your response should be sent to H. Tom Warwick, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087. If you have any further questions, please feel free to contact Mr. Warwick at (303) 236-3054.

Sincerely,

/S/

B. Belinda Collins
District Director